

Table 1. Demographic characteristics of the study population	
Age (years)	50.0 ± 10.0
Gender	
Male	50.0%
Female	50.0%
Education (years)	12.0 ± 2.0
Marital status	
Married	80.0%
Single	20.0%
Occupation	
Professional	30.0%
Managerial	20.0%
Technical	10.0%
Service	20.0%
Unemployed	20.0%
Income (USD/month)	1,000.0 ± 500.0
Health status	
Good	70.0%
Fair	30.0%

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[00001]** This application is a continuation of U.S. Patent Application Serial No. 09/415,776, entitled Percutaneous Bypass Graft and Securing System which claims benefit of U.S. Patent Application Serial No. 08/966,003, entitled Percutaneous Bypass Graft and Securing System, filed November 7, 1997, and U.S. Provisional Application Serial No. 60/030,733 entitled Percutaneous Bypass Graft and Securing System, filed November 8, 1996.

## BACKGROUND OF THE INVENTION

**[00002]** The present invention relates to grafts implantable to bypass an obstruction or other undesirable condition within a vessel or other tubular organ, and more particularly to systems for deploying such grafts and fixation elements for securing them.

**[00003]** Bypass grafts are particularly useful in treating vascular diseases, but have other applications including treatment of urinary incontinence, infertility, and gastrointestinal defects such as occlusions and ulcers. Stenosed vessels cause ischemia which potentially leads to tissue infarction. Conventional techniques to treat partially occluded vessels include balloon angioplasty, stent deployment, and surgery to attach a graft to bypass the stenosed lesion. Surgical implantation of a bypass graft typically requires performing a thoracotomy, placing the patient on a cardiopulmonary bypass system, and using cardioplegia to induce cardiac arrest. This permits a suturing of the graft between cardiac vessels without the risk of excess blood loss or the need to accommodate motion of the heart. Less invasive attempts at positioning bypass grafts involve a thoracostomy to produce a conduit to the stenosed lesion. This approach uses endoscopic visualization to position the graft. The delivery for such graft requires modified surgical instruments (e.g., clamps, scissors, scalpels, etc.) and further involves ports inserted through small (approximately one inch) incisions to provide access into the thoracic cavity.

[00004] There remains a need for a minimally invasive technique for deploying and securing a bypass graft, and for a fixation means for more reliably securing a graft without the need to suture the graft.

[00005] Accordingly, it is an object of the present invention to provide a system for transluminal deployment of a bypass graft.

[00006] Another object is to provide a more effective fixation means for securing a deployed bypass graft.

[00007] A further object is to provide a system for bypass graft deployment, in which features incorporated within the graft reduce the time and difficulty of deployment.

[00008] Yet another object is to provide an improved process for deploying and securing grafts along body lumens to bypass obstructions and other undesirable features within the lumens.

#### SUMMARY OF THE INVENTION

[00009] To achieve these and other objects, there is provided a body implantable graft. The graft includes a tubular graft wall having opposite first and second open ends. The graft defines a fluid flow lumen between these ends. The tubular graft is adapted for a selected placement with the first end at a first location in body tissue and the second end at a second location in body tissue, to provide a fluid flow path between the first and second locations to bypass an obstruction between those locations. The graft also includes a graft fixation mechanism operable to heat the graft wall at least near the first end following placement, to thermally secure the graft wall and adjacent tissue.

[00010] The preferred fixation apparatus is an electrically conductive heating element mounted to the graft wall near the first end. The element can be annular, and may incorporate a feature to mechanically secure the graft, e.g., a collet or a grommet.

**[00011]** In similar fashion an electrically conductive heating element or other fixation apparatus can be used to secure the second end of the graft at the second location. The heating elements can be coupled to an RF power source and used in conjunction with an indifferent electrode, to secure the graft by ohmic heating.

**[00012]** Another aspect of the invention is a system for deploying a bypass graft. The system includes an elongate and flexible carrier having a proximal end and a distal end. The carrier is insertable by the distal end for intraluminal movement toward a selected site along a body lumen while the proximal end remains outside the body. A tissue perforating mechanism, near the distal end of the carrier, is positionable at a first location near the selected site, and operable from the proximal end of the carrier to form a first opening through tissue at the first location. Further, the mechanism is positionable at a second location near the selected site and operable to form a second opening through tissue at the second location. An elongate graft guide, supported by the carrier and disposed near the distal end, is movable into a guiding position in which the guide extends from the first location through the first opening to the second location and through the second opening. The system further includes a tubular graft adapted to be mounted to the carrier for movement along the carrier. A graft controller is operable to move the graft distally along the carrier toward the graft guide, and then distally along the graft guide when the guide is in the guiding position, to a bypass location in which the graft extends from the first location to the second location and also extends through the first and second openings.

**[00013]** The preferred carrier is a catheter having a catheter lumen. An elongate dilator is contained slideably within the lumen, and has a tapered distal tip. An elongate needle is slideably contained within the dilator.

**[00014]** According to one embodiment, the dilator provides the graft guide, while the tissue perforating mechanism includes the needle and the distal tip of the dilator.

[00015] According to another embodiment, a distal end region of the catheter provides the graft guide. The dilator and needle are used to perforate and dilate tissue to form the first and second openings. The dilator is not used to guide the graft, but is used to guide the catheter, particularly the distal end region which in turn is used for positioning the graft after withdrawal of the dilator.

[00016] According to another aspect of the present invention, an alternative system is provided for implanting a bypass graft without the need for a catheter. This system includes a tissue dilating member having at its distal end a tissue dilating tip converging in the distal direction. A tissue puncturing tool is supported within the dilating member and extends in the distal direction from the dilating tip. The tool is adapted to puncture or perforate a tissue wall to form an orifice enlargeable by the dilating tip. The system includes a graft with a substantially fluid impervious graft wall. First, second and third openings are formed through the graft wall at first, second and third spaced-apart regions of the wall, respectively. The graft is adapted for a removable mounting on the dilating member in which the dilating member extends through the first and third openings, with the first opening near the dilating tip and the third opening proximally of the first opening. This enables use of the dilating member to insert the first region of the graft wall into a first orifice in the tissue wall, for fixation of the first region in the first orifice. The graft further is slideable relative to the dilating member to permit a proximal withdrawal of the dilating member from the first region after its fixation, and further to allow an insertion of the dilating member into the second opening for securing the second region of the graft wall within a second orifice in the tissue wall. As a result, the graft provides a fluid flow conduit between the first orifice and the second orifice. A closure mechanism is provided for closing the third opening, following withdrawal of the dilating member from the graft, after the first and second regions have been secured.

[00017] Another aspect of the present invention is a process for transluminally deploying a bypass graft, including the following steps:

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- a. advancing an elongate catheter intralumenally toward a selected site along a body lumen;
  - b. with a distal end of the catheter near the selected site, using a tissue perforating mechanism mounted near a distal end of the catheter to form a first opening through a tissue wall defining the body lumen;
  - c. advancing tissue perforating mechanism through the first opening, and then to a selected location spaced apart from the first opening, then using the mechanism to form a second opening through tissue at the selected location;
  - d. advancing a graft guide through the first opening, distally to the selected location, then through the second opening;
  - e. with the graft guide so positioned, advancing a tubular graft along the guide to a bypass location in which the graft extends from the first opening to the second opening and through the first and second openings, thus to form a bypass conduit in fluid communication with the body lumen; and
  - f. while maintaining the graft in the bypass location, proximally withdrawing the catheter, the tissue perforation mechanism and the graft guide.

[00018] Thus, in accordance with the present invention, bypass grafts are deployed more easily using techniques that are considerably less invasive, and upon deployment are more reliably secured.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[00019] For a further understanding of the above and other features and advantages, reference is made to the following detailed description and to the drawings, in which:

[00020] Figure 1 is a side view, partially in section, of a bypass graft constructed according to the present invention and secured within a vessel;

[00021] Figures 2-7 illustrate alternative couplings for mechanically fixing the opposite ends of bypass grafts;

- [00022]        Figure 8 illustrates an alternative embodiment graft incorporating structural supports;
  
- [00023]        Figures 9-16 illustrate alternative embodiment grafts incorporating valves;
  
- [00024]        Figures 17 and 18 are side sectional views of a bypass graft and system for securing the graft to a vessel wall, in accordance with the present invention;
  
- [00025]        Figures 19 and 20 illustrate tissue dilators of alternative embodiment deployment systems employing thermal bonding;
  
- [00026]        Figure 21 is a schematic illustration of a circuit for thermal bonding;
  
- [00027]        Figures 22-25 illustrate alternative embodiment dilators;
  
- [00028]        Figure 26 illustrates a tissue perforating needle used with the dilators of the various deployment systems;
  
- [00029]        Figure 27 is a sectional view of a needle and dilator contained within a catheter;
  
- [00030]        Figure 28 illustrates an alternative embodiment dilator within a catheter;
  
- [00031]        Figures 29a-h illustrate a series of steps of a percutaneous deployment and fixation of a bypass graft according to the present invention;
  
- [00032]        Figures 30a-d illustrate an alternative deployment and fixation procedure;
  
- [00033]        Figures 31a-c illustrate a further alternative deployment and fixation;
  
- [00034]        Figure 32 shows several bypass grafts secured to the heart; and

[illegible]

## DESCRIPTION OF THE INVENTION

[00036] Turning now to the drawings, there is shown in Figure 1 a bypass graft 16 secured within a blood vessel 18, in a manner to bypass a lesion 20 within the vessel. Bypass graft 16 has a tubular wall 22 formed of a graft material, e.g., a polymer such as PTFE, urethane, polyimide, nylon, silicone, or polyethylene. The polymer may be extruded, blow molded, or dipped, and formed either directly into a tubing, or formed first as a sheet having opposed ends or edges bonded together to provide the tubular configuration. The edge bond can be formed by a variety of methods including ultrasonic welding, thermal bonding, sewing, adhesives, or with radio frequency (RF) energy. Alternatively, the graft can be a saphenous vein or other vessel from the patient.

[00037] At its proximal end 24, bypass graft 16 incorporates a radially expandable stent 26. The graft incorporates a similar stent 28 at its distal end region 30. Once graft 16 is deployed, the stents are radially expanded using a dilatation balloon or a mechanism such as those described in co-pending patent application Serial No. 08/911,838 entitled "Mechanical Stent and Graft Delivery System," filed August 15, 1997. Alternatively, the graft end regions can have a self-expanding structure, as described in co-pending patent application Serial No. 08/932,566 entitled "Radially Expanding Prostheses and Systems for Their Deployment," filed September 19, 1997. In either event, each stent and its surrounding graft material are expanded into intimate contact with wall 22 of vessel 18, thus to secure the graft.

**[00038]** As seen in Figure 1, graft 16 bypasses lesion 20, in the sense that a medial region 32 of the graft is disposed outside of vessel 18. For convenience, the graft can be considered to exit the vessel at an exit opening or orifice 34 through vessel wall 35, and re-enter the vessel at a return opening or orifice 36.

**[00039]** Tubular bypass grafts such as graft 16 can be secured within vessel walls or to other tissue by a variety of fixation mechanisms other than expandable stents. For example, Figure 2 illustrates an annular collet 38 attached to one end of a graft 40. The collet may be laminated or bonded to the graft, and is pre-formed to have a segment 42 extending radially beyond the graft. Segment 42 also is collapsible into a low profile to facilitate introduction through vasculature and deployment through the vessel wall. When released, the collet assumes the pre-formed configuration as shown. A portion 44 of the graft may extend along collet segment 42 to secure the vessel wall between the graft material and the collet and provide additional support for attaching the graft to the vessel.

**[00040]** Figures 3 and 4 illustrate a collet 46 in which the radially extending collet segment is comprised of eight radially extended collet members 48. A membrane 50 may be joined to the collet members to prevent fluid flow through the tissue wall puncture site.

**[00041]** Figure 5 shows a further alternative support mechanism in the form of an annular grommet 52 secured to end region 54 of a graft 56. The grommet incorporates a convergence 58 to facilitate insertion through a vessel wall orifice, and a necked down feature 60 to capture the vessel wall immediately about the orifice.

**[00042]** As yet another mechanical fixation alternative, flexible bands 62 can be fixed to an end region of a graft 64 as shown in Figures 6 and 7. Each band or other flexible member is compressible into the reduced profile shown in Figure 6 and remains in that profile while constrained, e.g., by a surrounding catheter. When the graft is released from the catheter, band 62 assumes the radially enlarged, more circular profile shown in Figure 7. Pluralities of such bands can be provided in crossing patterns at the graft ends, if desired.

**[00043]** For increased strength, particularly where a bypass graft is required to exert a radially outward force against a stenosed lesion, a blood vessel wall or other tissue, the graft can incorporate structural support members 66. The support members can be constructed of metal or a polymer having a higher modulus of



elasticity than the graft material. As shown in Figure 8, support members 66 can be distributed throughout the graft, with a greater density at the graft end regions to enhance fixation within openings through tissue. Support members 66 can have elliptical or rectangular profiles that enhance their strength in a selected direction.

**[00044]** If desired, such support members can be used in lieu of stents 26 and 28 for securing graft ends within a vessel. The support members may be laminated in the graft material. Fabrication can involve extruding or dipping an initial graft layer, winding the support members on the layer, then extruding or dipping to form a second layer covering the support members. Alternatively, the separate layers may be bonded together, or support members may be threaded through the graft material.

**[00045]** If desired, thermal bonding may be employed to augment the mechanical fixation and form a more positive fluid seal. More particularly, electrode strips 68 are mounted to the graft near the graft ends, and coupled through wires 70 to an energy source (e.g., an RF generator) which generates a current to heat adjacent tissue. When sufficient energy is supplied to the electrodes, the graft edges are thermally secured to the vessel all by a coagulation of the tissue to the electrode, or by desiccation of the vessel wall to provide an interference fit between the reduced-diameter vessel and the graft, especially where the graft and support members exert a radial force. This better secures the graft to the vessel wall and prevents leaks at the graft edges. Suitable materials for the electrodes, which are body compatible as well as electrically conductive, are platinum, platinum-iridium, stainless steel, and gold.

**[00046]** Once the graft has been sealed, signal wires 70 are removed from the graft by delivering a D.C. current through the signal wires at an amplitude sufficient to cause a breakdown of the signal wire, e.g., at a reduced-diameter weak point near its associated electrode. Alternatively, the signal wire can be cleaved, or mechanically removed by applying tension to sever the wire at a reduced-diameter neck region.

**[00047]** On occasion, it is desirable or necessary to ensure that flow of blood or other fluids through the graft is uni-directional. To this end, a valve may be placed

within the graft, preferably along the medial region. Figures 9-16 show a variety of graft constructions.

[00048] Turning first to Figures 9 and 10, a valve 72 includes a valve ball 74 within a surrounding structure that provides a valve seat 76 on one side of the ball, and upper and lower retainers 78 and 80 on the other side of the ball. In Figure 9, the valve is open and allows flow in the direction of the arrows, around the valve ball and through open spaces between the valve ball and surrounding structure in the area not occupied by the upper and lower retainers.

[00049] As shown in Figure 10, flow in the opposite direction is substantially prevented by a lodging of ball 74 against the valve seat. Further, the valve functions as a pressure relief valve in that the flow from left to right as viewed in the figure must be sufficient to overcome the tendency of retainers 78 and 80 to urge the ball valve against the valve seat.

[00050] Figure 11 shows a valve 82 designed to react to the muscular contraction to restore normal vessel function. Muscular contraction forces the valve ends inward, opening the valve to permit fluid flow. The force required to open the valve may be selected, depending on the material, wall thickness, length, and geometry. A solid valve requires more force than a valve in which material is selectively removed to maintain the valve function yet decrease the required compressive force to open the valve.

[00051] Figures 12-14 show a one-way valve 84 having a membrane 86 that closes over valve support struts 88 when no external pressure is present. When pressure is applied due to a fluid flow, membrane 86 distends outwardly away from the struts as seen in Figure 14, permitting the flow of fluids. Fluid flow in the opposite direction (right to left as viewed in Figures 12 and 14) is prevented.

[00052] The valves in Figures 9-10 and 12-14 act as pressure relief valves, in the sense that they may be tailored to require a selected force to open them, and they remain open only when the applied pressure exceeds the valve resistance. As a result,

these valves characteristically remain open for short periods of time. Alternatively, Figures 15 and 16 show a pressure relief valve 90 that opens due to pressure exerted on the valve, and remains open until a compressive closure force is applied. Valve 90 includes a plunger 92 movable within a surrounding structure including a valve seat 94 and a knob structure 96 for retaining the valve against the valve seat. The outer structure, which can be the graft itself, includes a flexible section 98 including a protrusion 100 that can be flexed radially inwardly responsive to external pressure.

**[00053]** The knob structure maintains the valve closed until pressure against the valve, i.e., acting from left to right as viewed in Figure 16, exceeds a selected threshold and opens the valve to allow rightward flow. Even after such pressure subsides, the valve remains open until external, radially inward pressure is applied to compress flexible section 98 of the graft. This moves the plunger leftward, returning it beyond the knob structure against the valve seat, thus closing the valve once again.

**[00054]** Valve 90 is particularly well-suited for treating urinary incontinence. When bladder pressure exceeds the relief valve pressure threshold, the valve is opened to permit the flow of urine. When the bladder pressure is relieved, muscular contractions or other external squeezing flexes section 98 to return plunger 92 to the valve seat, thus closing the valve.

**[00055]** Systems for deploying grafts may require an incision, or alternatively may involve transluminal delivery for a substantially noninvasive procedure. In the latter case, the system must restrain the graft during introduction through sheathes positioned via the Seldinger technique or a surgical cut-down, advancement through the vasculature and into the target vessel. Unwanted perforations of the vessel or other tissue must be avoided. This requires flexibility to follow a guide wire positioned in the target vessel. Further, the system must facilitate easy and accurate deployment of the graft and delivery components. If a partially deployed graft needs to be altered as to location, the system should permit recapture and repositioning. Graft delivery systems may incorporate the capacity to mechanically create intimate contact of the graft with surrounded tissue, especially at the graft ends. This

capability is discussed in the aforementioned application Serial No. 08/911,838 entitled "Mechanical Stent and Graft Delivery System."

[00056] Figures 17 and 18 show a bypass graft deployment system 102 that requires an incision. The system includes a dilator 104 having a tapered (distally converging) distal tip 106. A needle 108 is mounted coaxially within the dilator, and has a sharp cutting edge 110 for puncturing or perforating tissue. A bypass graft 112, having a grommet 114 or other suitable fixation mechanism, is supported on and surrounds the dilator.

[00057] Use of system 102 requires an incision characteristic of a surgical cut-down, through the dermal layers near the vessel to provide an insertion port. Needle 108, which can be slideably contained within the dilator if desired, is introduced into the insertion port and punctures a wall 116 of a vessel 118 on one side of a stenosed lesion 120. The dilator then is advanced over the needle to enlarge the puncture to provide an orifice for fixation of the graft. At this point, graft 112 is advanced over the dilator sufficiently to position grommet 114 within the orifice. Thus, a first region 122 of the graft is secured, so that an opening 124 of the graft is in fluid communication with vessel 118.

[00058] As seen in Figure 18, graft 112 has two further openings: an opening 126 surrounded by graft material and a second grommet 128; and a more proximally disposed opening 130, where no grommet or other fixation device is provided.

[00059] Progress from the view of Figure 17 to the view of Figure 18 involves, in part, securing region 122 and grommet 114 as just described. Next, dilator 104 and needle 108 are withdrawn proximally, sufficiently to remove them from region 122. Then, the dilator and needle are distally inserted through opening 126, to become surrounded by grommet 128 and a graft region immediately about opening 126 as shown in Figure 18. At this point, needle 108 is advanced to puncture tissue wall 116, and dilator 104 is used to enlarge the puncture, to form a second orifice on the opposite side of lesion 120. Then, as shown in Figure 18, the dilator and graft are advanced sufficiently to position grommet 128 within the orifice.

**[00060]** After grommet 128 is secured, the dilator and needle are withdrawn from opening 126, and further are withdrawn from a region 132 of the graft surrounding opening 130 so that the dilator and needle are completely free of the graft. Then opening 130, which is provided only to allow access of the dilator and needle, is closed to prevent fluid leakage from the graft. One suitable closure mechanism is a purse-string, formed by threading a suture through the graft material in region 132. Other closure mechanisms include staples or adhesives.

**[00061]** In multiple lumen applications, the bypass graft may have four or more openings to accommodate three or more fluid couplings to vasculature or organ cavities.

**[00062]** Alternative embodiment deployment systems use different approaches for graft fixation. For example, Figure 19 shows a dilator 136 with a central lumen 138 for a needle (needle not shown). The dilator also incorporates a lumen 140, through which a signal wire can extend for coupling with a dilator electrode 142. Electrode 142 delivers RF energy to a grommet 144 at the distal end of a graft 146 surrounding the dilator, thus to thermally secure the grommet to a tissue wall 148 of a vessel 150.

**[00063]** In Figure 20, a dilator 152 includes, along with a central needle lumen 154, a signal wire lumen 156 and a balloon inflation lumen 158 open to a balloon 160 near the distal end of the dilator. The dilator supports a surrounding graft 162 having a collet 164 at its distal end.

**[00064]** Following insertion of the dilator through wall 166 of vessel 168, balloon 160 is inflated to temporarily secure the dilator, which also bends a portion of collet 164 into the retaining position as shown. An electrode 170, mounted on the exterior of balloon 160, receives a current from a signal wire contained in lumen 156, for thermally bonding collet 164 to the surrounding tissue. After thermal bonding, the balloon is deflated and the dilator withdrawn.

[00065] Figure 21 illustrates a schematic circuit for ohmic heating of tissue, useable in conjunction with electrode 170, other dilator supported electrodes, or electrodes mounted directly to a graft as previously described. An RF power generator 174 is coupled to the electrode through a signal wire 176. An indifferent electrode 178, spaced apart from electrode 170 and typically placed on a patient externally, is coupled to the RF generator through a conductor 180. Thus, a current is generated through tissue between electrodes 170 and 178, heating the tissue to form the bond.

[00066] Figures 22 and 23 are sectional views of a distal region of a dilator 182, taken at different angles to show different lumens through the dilator. Lumens 184 and 186 in Figure 22 accommodate signal wires to sensors or transducers 188 and 190 (further discussed below), which can be used to direct placement of the dilator at puncture sites. Sensor 188 is positioned for axial sensing, while a sensor 190 is oriented for lateral sensing. Several sensors 190 can be angularly spaced apart from one another about the dilator circumference.

[00067] Lumens 192 and 194, shown in Figure 23, accommodate signal wires 196 to electrodes 198 used for thermal bonding.

[00068] As shown in Figure 24, a steering mechanism can be incorporated into the dilator to facilitate positioning of the dilator and needle for tissue perforations. In particular, a ring 198 is embedded in the dilator distal tip, surrounding needle lumen 200. A wire 202 is attached to ring 198. By pulling wire 202, the distal tip can be biased downwardly as viewed in the figure.

[00069] To further assist positioning, magnets may be incorporated into the dilator near its distal tip, as indicated at 206 for a dilator 208 shown in Figure 25. Such magnets may be formed of ferrite materials, or alternatively may be formed by winding conductive coils around the dilator to form electromagnets when current is supplied. The dilator magnets are used in conjunction with a guide wire 209 advanced beyond a stenosed lesion 210 within a vessel 212. The guide wire is formed of metal, and to further enhance magnetic attraction may incorporate a

magnet 214 of opposite polarity to the dilator magnet. Magnetic positioning facilitates placing bypass grafts through tortuous vessels or over long distances beyond the lesion. Alternatively, known imaging techniques can be used to locate the dilator magnets.

[00070] As seen in Figure 26, a needle also can be provided with steering capability, in particular by forming a hollow needle 216 and securing a wire 218 to a distal portion of a needle through a weld or solder joint 220. A sensor 222 at the needle tip, coupled to wires 224 contained within the needle lumen, can be used to sense a position of the needle tip. A further needle enhancement is a stop 226. When open as shown in Figure 26, stop 226 limits the degree to which needle 216 can be inserted into tissue, thus preventing excessive, damaging perforations. At the same time, stop 226 is collapsible into a diameter substantially the same as that of the needle when the needle is withdrawn into a dilator.

[00071] Intraluminal graft deployment systems also utilize dilators and needles as described, but further incorporate catheters. A suitable arrangement, as shown in Figure 27, includes a needle 228 surrounded by a dilator 230, which in turn is surrounded by a catheter 232, all components being coaxial and circular in profile.

[00072] An alternative arrangement, shown in Figure 28, incorporates non-circular features into a dilator 234 and a lumen of a catheter 236. The non-circular matching features allow transmittal of torque from catheter 236 to dilator 234, enabling selective rotation of the dilator by rotating the catheter.

[00073] Figures 29a-29h illustrate progressive steps in a percutaneous, intraluminal deployment of a graft 238, to bypass a lesion in a vessel 240. The system includes a catheter 242 with a lumen 244 containing graft 238, a dilator 246 and a needle 248 within the dilator.

[00074] First, the catheter and other components are advanced intralumenally to the proximal side of lesion 250 as shown in Figure 29a. Sensors 252 facilitate positioning. Such sensors can include ultrasonic transducers of piezoelectric

material, infrared transducers, or fiber-optic elements. Alternatively, a radiopaque contrast material may be injected to enhance fluoroscopic visualization.

[00075] As seen in Figure 29b, needle 248 is advanced to puncture vessel wall 254. A stop 256 restricts movement of a needle if necessary. Then, dilator 246 is advanced, collapsing stop 256 and enlarging the puncture to provide a suitable orifice through the vessel wall. The orifice and dilator tend to form a seal, preventing excess blood leakage as the dilator is advanced along and outside of the vessel. The dilator may have a pre-shaped distal end to facilitate positioning, as shown in Figure 29c.

[00076] When the dilator has been advanced to a point near a selected re-entry location, needle 248 is advanced beyond the dilator to puncture vessel wall 254 (Figure 29d). Once again, stop 256 prevents excessive needle advancement, if necessary. Alternatively the stop can limit needle travel relative to the dilator. At this point, dilator 246 is advanced over the needle (Figure 29e), collapsing the stop and enlarging the puncture by its distal tip, entering the vessel once again. At this time, needle 248 may be completely retracted if desired.

[00077] As seen in Figure 29f, graft 238 then is advanced over dilator 246, until the graft reenters the vessel, i.e., has its opposite ends contained, each in its respective orifice. A collet 258 at the distal end of the graft prevents graft retraction, and a collet 260 anchors the proximal end of the graft. At this point, the dilator can be retracted back into catheter 242, as shown in Figure 29g. A hollow stylet 262 is used to advance the graft, and also to maintain the graft in place during subsequent withdrawal of the dilator. Finally, the catheter, stylet and dilator are withdrawn, leaving graft 238 secured, as seen in Figure 29h.

[00078] Figures 30a-d show an Alternative system and graft deployment process, in which a graft 264 is guided to its bypass location within a catheter rather than over a dilator. The system includes a catheter 266 containing a dilator 268, which in turn contains a puncturing needle 270. These components are advanced to a position proximate a lesion 272 within a vessel 274. Dilator 268 is pre-formed with a bend at its distal region, and when positioned as shown in Figure 30a, is directed



upwardly toward the vessel wall as shown, to direct the needle toward the first intended puncture.

[00079] After puncture and dilation with the dilator tip, dilator 268 can be advanced over the needle, outside of and along the vessel. The dilator is rotated, preferably by the catheter using non-circular profile features as described above, to reorient the tip and point it back toward the vessel as shown in Figure 30b. Catheter 266 is advanced along the dilator, through the orifice and outside of the vessel. A balloon 276 surrounding the catheter can be inflated at this point, to maintain the catheter against proximal withdrawal.

[00080] Then, with the tip of dilator 268 positioned against the vessel wall at the desired puncture location, needle 270 is advanced to form the puncture for a re-entry orifice (Figure 30c). The dilator tip is used to enlarge the orifice, permitting advancement of the dilator into vessel 274, followed by advancement of catheter 266 over the dilator, through the orifice and into the vessel as well. Balloon 276 can be reinflated at this point, to temporarily secure the catheter.

[00081] With the catheter secured, the dilator and needle are withdrawn, leaving the catheter alone as in Figure 30d. At this stage, and after withdrawal of the dilator and needle, a graft can be inserted into the catheter and moved distally along the catheter using a stylet 278, until the graft reaches a bypass location in which each end of the graft is contained within its respective orifice. Withdrawal of the catheter (not shown), while the stylet maintains the graft in the bypass location, allows collets or other fixation mechanisms to expand and secure the graft.

[00082] This procedure is particularly suited for smaller lesions, where the dilator need travel only a short distance along the vessel.

[00083] Figures 31a-c illustrate a further alternative system and procedure for forming a bypass from a vessel to an organ cavity. Initially, a catheter 280 containing a dilator 282 and a needle 284 is advanced to an intended puncture site 286 within a vessel 288. The puncture is formed as previously described, and the dilator is

advanced through tissue to an organ cavity 290. Then, the catheter is advanced over the dilator, becoming open to the cavity as shown in Figure 31b. This permits use of a stylet 292 to advance a graft 294 through the catheter, until the catheter extends completely through the tissue to the cavity. Collets 293 and 295 secure the catheter. A valve 296 within the catheter limits flow to the direction indicated by the arrow. A graft 298 incorporating a valve 300 is positioned near lesion 302, to prevent backflow toward the lesion.

[00084] Figure 32 illustrates two bypass grafts 304 and 306 used to couple the aorta to coronary vasculature in accordance with the present invention.

[00085] Figure 33 illustrates a graft 306 collapsed around a catheter body 308, deployed in a target vessel across a stenosed lesion 310. The catheter and graft are translumenally advanced to the position shown. The opposite ends of the graft contain expandable stents 314 and 316, expanded in place with a mechanism such as those described in the aforementioned application Serial No. 08/911,838. Alternatively, the graft ends can have self-expanding characteristics.

[00086] Figure 34 shows the graft expanded. The ends are fully expanded into intimate contact with the vessel wall. However, along a medial region 318, graft 306 is expanded only to a nominal diameter. The diameter is selected to reduce the flow of resistance and increase cardiac output, yet prevent damage to the endothelial wall. For example, a 50% expansion usually is sufficient to open the vessel while preventing excess damage. A large space between the exterior of the graft and the vessel wall accommodates growth of the stenosed lesion, and tends to contain such growth along the vessel wall so that the vessel remains open. To accomplish this, graft 308 should have inherent radial stability, for example, by employing structural supports as previously discussed.

[00087] If desired, graft structural stability and fixation can be enhanced by forming grafts with two or more layers, with pockets formed between the layers to contain biocompatible foams which solidify when activated to provide further support. Drug solutions also can be provided in such pockets.

[00088] To improve graft radial expansion in conjunction with using the graft of Figures 33 and 34, channels may be formed through the lesion by cutting a slit through the vessel wall in the targeted region. A mechanical deployment system as described in the aforementioned patent application Serial No. 08/911,838 can be used to form the required channel.

[00089] Thus, in accordance with the present invention, a more easily deployed graft is more reliably secured, to effectively bypass lesions and other blockages.

[00090] The patent applications cited herein are incorporated by reference, each in its entirety and for all purposes.